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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/551,874

05/07/2007

Stefan Russwurm

3535-027

3945

30448

7590

08/20/2008

AKERMAN SENTERFITT

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EXAMINER

KAPUSHOC, STEPHEN THOMAS

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/551,874	<b>Applicant(s)</b> RUSSWURM ET AL.	
	<b>Examiner</b> Stephen Kapushoc	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____.                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____.  | 6) <input type="checkbox"/> Other: ____.                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group 1, claim(s) 1, 4-12, and 15-29, drawn to RNA expression based methods for detection of SIRS.

Group 2, claim(s) 2 and 13, drawn to RNA expression based method for detection of sepsis and/or sepsis-like conditions.

Group 3, claim(s) 3 and 14, drawn to RNA expression based methods for detection of severe sepsis.

Group 4, claim(s) 30, 33-39, and 42-56, drawn to peptide based methods for detection of SIRS.

Group 5, claim(s) 31 and 40, drawn to peptide based methods for detection of sepsis and/or sepsis like syndrome.

Group 6, claim(s) 32 and 41, drawn to peptide based methods for detection of severe sepsis.

### **Further Lack of unity Restriction Requirement**

If Applicants elect the invention of Group 1 or Group 4, Applicants shall further select: (i) a single specific combination of genes from the group consisting of SEQUENCE ID No. III.1 to SEQUENCE ID No. III.4168 (as recited in claims 12 (applicable to Group 1) and 39 (applicable to Group 4)); or (ii) the combination of SEQUENCE ID No. III.1 to SEQUENCE ID No. III.4168 SEQUENCE ID No. I.1 to SEQUENCE ID No. III.6242 and SEQUENCE ID No. II.1 to SEQUENCE ID No. II.130 (as recited in claim 20 applicable to Group 1).

If Applicants elect the invention of Group 2 or Group 4, Applicants shall further select a single specific combination of genes from the group consisting of SEQUENCE

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ID No. I.1 to SEQUENCE ID No. III.6242 (as recited in claims 13 (applicable to Group 2) and 40 (applicable to Group 5)).

If Applicants elect the invention of Group 3 or Group 6, Applicants shall further select a single specific combination of genes from the group consisting of SEQUENCE ID No. II.1 to SEQUENCE ID No. II.130 (as recited in claims 14 (applicable to Group 3) and 41 (applicable to Group 6)).

In each case as detailed above for Groups 1-6, claims requiring specific genes will only be examined if they recite the genes of the selected particular combination; and those claims will only be examined in so far as they require the selected combination. Claims requiring only genes that are not in the selected combination will be withdrawn as to a non-elected invention. Generic claims will be examined to their full generic extent. For the selected particular combination of genes, Applicants should fully identify the selected genes by and identifiers used in the instant application, including 'SEQUENCE ID No.' as recited in the claims, SEQ ID NO: from the sequence listing, gene name and gene symbol, and indicate where the genes are included in the application (i.e. any pages, Tables, or figures from the specification).

2. The inventions listed as Groups 1-6 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

3. The common technical feature among the different groups are genes which are associated with the various sepsis related conditions of the claims. However this type of association was known in the prior art. For example, Chinnaiyan et al (1999) as cited on the IDS of 3/15/2006, teaches the analysis of gene expression in a rat sepsis model (p.1201 – Profiling sepsis using high-density rat cDNA microarrays) indicating genes and the encoded polypeptides (p.1204 – Fig 3) that are associated with sepsis. As such, the common technical feature among the different groups is not a special technical feature.

4. With regard the to Further Lack of unity Restriction Requirement, the different genes and their encoded polypeptides are different as they are composed of unique polynucleotide and polypeptides sequences that are structurally distinct. Thus the different genes and their encoded polypeptides do not share any common structural elements associated with their asserted functionality of being associated with the various sepsis related conditions.

5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Kapushoc whose telephone number is 571-272-3312. The examiner can normally be reached on Monday through Friday, from 8am until 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days.

Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Stephen Kapushoc/  
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